UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re: BAIR HUGGER FORCED AIR WARMING DEVICES PRODUCTS LIABILITY LITIGATION	MDL No. 15-2666 (JNE/FLN)
This Document Relates to All Actions	**ORDER**

This matter is before the Court pursuant to the District of Minnesota's Local Rule 72.2(a)(3), which provides for review of objections to a magistrate judge's order on nondispositive matters. Plaintiffs in this multidistrict litigation ("MDL") filed a Motion to Overrule VitaHEAT Medical LLC's Relevancy Objection to Subpoena [Dkt. No. 218], seeking a ruling on the relevancy of discovery they seek from third party VitaHEAT Medical LLC ("VitaHEAT"). MDL Defendants and VitaHEAT jointly opposed the motion. *See* Dkt. No. 236. After holding a hearing, the Honorable Franklin L. Noel, United States Magistrate Judge, denied the motion. Dkt. No. 249 ("Order"). Plaintiffs timely objected. The Court must modify or set aside any objected-to part of the Order that is clearly erroneous or is contrary to law. 28 U.S.C. § 636(b)(1)(A); Fed. R. Civ. P. 72(a); D. Minn. L.R. 72.2(a)(3). Having reviewed the record, the Court affirms.

Plaintiffs subpoenaed VitaHEAT for the production of documents relating to VitaHEAT's product the "UB3 patient-warming system," a medical device that uses conductive heat to warm patients ("UB3"). *See* Pls.' Mem. 1, Dkt. No. 220; Sacchet Decl. Ex. N, Dkt. No. 221-14 (subpoena). VitaHEAT objected to the subpoena as overly broad and unduly burdensome, as well as on the grounds that Plaintiffs had not shown that the requested documents were relevant. *See id.* Ex. O, Dkt. No. 221-15 (VitaHEAT objections). During the meet-and-confer process, Plaintiffs represented that they had identified the "UB3, among other

conductive warming devices, as a safer alternative design to the [Defendants'] Bair Hugger forced-air warming system at issue in this litigation." Conlin Decl. ¶ 7, Dkt. No. 222. VitaHEAT objected that the UB3 is not an alternative design to the Bair Hugger because the UB3 is a different product, not a different design of the same product. *See id.* ¶ 12.

Plaintiffs moved for an order "ruling that Federal Rules of Civil Procedure 26(b)(1) and 45(d)(2)(B)(i) govern VitaHEAT Medical, LLC's relevancy objection to the subpoena" and "determining that VitaHEAT Medical, LLC's relevancy objection has no basis in fact or law." Dkt. No. 218. They argued that their discovery requests sought documents relevant to their allegations that an "economically and technologically feasible and safer alternative design existed for the Bair Hugger, including but not limited to airflow-free warming technologies . . . ." Plfs.' Mem. 9; Am. Master Compl. ¶ 95, Dkt. No. 97. Other references to alternative designs in the pleadings are more general. *See, e.g.*, Am. Master Compl. ¶¶ 10 ("safer alternative designs"), 52 & 61 (same), 114 ("other alternative devices"), 128 ("safer alternative warming devices"). In support of their argument, Plaintiffs relied on multiple documents that they submitted with their brief, including: an internal email by a 3M Company executive which they contend supports their theory; materials on VitaHEAT's former website; a VitaHEAT press release; a § 510(k) summary that VitaHEAT submitted to the Food and Drug Administration ("FDA") for authorization to market the UB3; and what appears to be a study comparing the effectiveness of forced-air warming devices and conductive heating devices for patient warming. *See id.* at 11-14. Plaintiffs acknowledged that the Bair Hugger and the UB3 use different "type[s] of heating technology." *Id.* at 14 n. 50. They argued, however, that forced-air warming devices and conductive heating devices are simply alternative versions of the same product, a patient-warming device, as alleged in their Amended Master Complaint.

The magistrate judge found that the Bair Hugger forced-air warming device and a patient warming device that uses conductive heating, like VitaHEAT's UB3 device, use "fundamentally different types of technology" and are "substantially different products." Order, at 2. Therefore, the magistrate judge found, Plaintiffs are not entitled to the discovery they seek from VitaHEAT because it is not relevant. *Id.*

Plaintiffs' objections do not convince the Court that the Order contains any clear error or mistake of law. It was Plaintiffs' burden to establish a "threshold showing of relevance." *Hofer v. Mack Trucks, Inc.*, 981 F.2d 377, 380 (8th Cir. 1992). "While the standard of relevance in the context of discovery is broader than in the context of admissibility . . . , this often intoned legal tenet should not be misapplied so as to allow fishing expeditions in discovery." *Id.*

As an initial matter, the Court questions the propriety of Plaintiffs' request for a standalone relevancy determination. A motion to compel discovery, in contrast, would involve weighing relevancy against burden and other proportionality factors. *See* Fed. R. Civ. P. 26(b)(1). "The court's responsibility, using all the information provided by the parties, is to consider these and all the other factors in reaching a case-specific determination of the appropriate scope of discovery." Advisory Comm. Notes to 2015 Amendment of Fed. R. Civ. P. 26. Plaintiffs now complain that the magistrate judge prematurely ruled that conductive heating devices are not an alternative design to the Bair Hugger forced-air warming device, but they teed up that ruling by filing the motion styled as it was.

Plaintiffs first object that the Order contains erroneous factual findings. The Court concludes that Plaintiffs have not demonstrated any clear factual error based on the record before the magistrate judge. The magistrate judge relied on the declaration of Albert Van Duren, a 3M Company manager with responsibilities in its patient warming business, to find that the Bair

Hugger forced-air warming system and the UB3 conductive heating device used different types of technology. Order at 2. Plaintiffs admitted this fact in their briefing before the magistrate judge. Pls.' Mem. 14 n. 50 (stating that "[t]he only difference between the Bair Hugger and the UB3 is the type of heating technology"). The magistrate judge also cited Plaintiffs' overarching theory that the technology inherent to the Bair Hugger—that is, forced-air, convective heating—is more dangerous than the technology in conductive heating devices, which do not use convective heating. Order, at 3. Indeed, the whole thrust of Plaintiffs' allegations is that the Bair Hugger's air-blowing technology is what causes infections. *See, e.g.*, Am. Master Compl. ¶¶ 3-8. Plaintiffs reinforce this point by referring to the Bair Hugger as a "forced air warming device." *See, e.g., id.* ¶¶ 1, 40; Conlin Decl. ¶ 7. Based on this record, it was not clear error to conclude that a forced-air warming device is a different product using different technology than a conductive heating device.

Plaintiffs' arguments as to factual error largely rely on facts not before the magistrate judge. In their objection, Plaintiffs submitted a copy of a § 510(k) summary that appears to have been filed by Augustine Biomedical & Design, LLC to receive FDA approval to market the Hot Dog Patient Warming System, another conductive heating device. *See* Dkt. No. 281-1. Plaintiffs assert that the UB3 was found to be substantially equivalent to the Hot Dog, and that the Hot Dog was found to be substantially equivalent to the Bair Hugger, and that these findings demonstrate the relevance of Plaintiffs' discovery requests. *See* Pls.' Obj. 5-6, Dkt. No. 279. The Court will not consider new evidence that was not submitted to the magistrate judge for consideration. *See Roberts v. Apfel*, 222 F.3d 466, 470 (8th Cir. 2000); *Peerless Indem. Ins. Co. v. Sushi Ave., Inc.*, No. 15-CV-4112 (ADM/LIB), 2017 WL 631547, at *4 (D. Minn. Feb. 15, 2017). Plaintiffs were on notice of the argument that conductive heating devices and forced-air

warming devices were different products, *see* Pls.' Mem. 7, 14 n.50; Conlin Decl. ¶ 12, and they could have presented this evidence to the magistrate judge. There is no error in not considering a document that Plaintiffs failed to submit for consideration.[1] Similarly, Plaintiffs argue that testimony that was elicited in a deposition *after* the magistrate judge already ruled demonstrates that the Bair Hugger and the UB3 do not use different types of technology. *See* Pls.' Obj. 7 (citing to Dkt. No. 268). Even if the Court were to consider this new evidence, it would not find clear error because the testimony, read in full, does not say what Plaintiffs want it to say.

Plaintiffs also argue that the magistrate judge erred as a matter of law because the question of whether conductive heating devices are reasonable alternative designs should be reserved for summary judgment or trial. They cite no controlling case law on this point. They discuss several cases in which the court declined to decide the alternative-design-versus-alternative-product question. *See* Pls.' Obj. 8-9. But those decisions involved different procedural postures. For example, *Sec. Nat'l Bank of Sioux City v. Abbott Labs.*, No. 11-cv-4017-DEO, 2012 WL 327863, *1 (N.D. Iowa Feb. 1, 2012), and *Burks v. Abbott Labs.*, No. 08-cv-3414 (JRT/JSM), 2010 WL 1576779, at *1 (D. Minn. Apr. 20, 2010), are unremarkable because in each case, the court was deciding a motion to dismiss and was thus unable to look beyond the pleadings. Here, Plaintiffs themselves asked the magistrate judge to consider numerous documents outside the pleadings.

[1] Furthermore, an FDA finding of substantial equivalence in the § 510(k) premarket approval process does not necessarily mean that the device under consideration has the same technological characteristics as the predicate device. *See* 21 C.F.R. § 807.100(b)(ii)(A); *see also Medtronic, Inc. v. Lohr*, 518 U.S. 470, 492-93 (1996) (describing the § 510(k) review process as something less than a formal review for safety or efficacy). As Plaintiffs note, *In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig.*, No. 4:08-md-2004 (CDL), 2010 WL 234797 (M.D. Ga. Jan. 14, 2010), also involved § 510(k) summaries and third-party discovery requests. The decision does not help them, though, because that court's threshold relevancy determination relied on the third party's concession that its product was an alternative design to the allegedly defective product. *See id.* at *2.

In addition, Plaintiffs argue that the magistrate judge erred as a matter of law in determining that a different product cannot be a safer alternative for purposes of design defect liability. Again, they do not cite any controlling authority that makes the magistrate judge's conclusion contrary to law. Plaintiffs quote part of a comment in the Restatement (Third) of Torts that "[f]urthermore, other products already available on the market may serve the same or very similar function at lower risk and at comparable cost," and that "[s]uch products may serve as reasonable alternatives to the product in question." Restatement (Third) of Torts § 2 cmt. f (Am. Law Inst. 1998). These remarks, however, relate to an inapposite hypothetical discussion about expert testimony for an obvious design alternative to removable hard buttons on a toy, and thus do not appear pertinent. Other comments in the Restatement appear to support the magistrate judge's ruling. The Restatement indicates that it is appropriate for a court to characterize what the product at issue is, which necessarily affects a determination of what a reasonable alternative design to that product is. *See id.* cmt. e; *cf. Hofer*, 981 F.2d at 381 (conducting a "fact[-]specific determination of the extent of the similarities or dissimilarities" between an allegedly defective product and an older model about which plaintiff sought discovery, "inquir[ing] about the basis for the discovery request," and affirming denial of the discovery request where the product models were "sufficiently dissimilar in design").[2] Moreover, Defendants and VitaHEAT point to a case in which the district court granted a motion to dismiss because it determined that the plaintiff's proposed alternative was a different product, not an alternative design. *Massa v. Genentech, Inc.*, Civ. No. H-11-70, 2012 WL 956192, at *7 (S.D. Tex. Mar. 19, 2012); *see also Simon v. Smith & Nephew, Inc.*, 990 F. Supp. 2d 395, 405

[2] Although the *Hofer* court noted in *dicta* that "discovery *may* be allowed where a plaintiff alleges . . . that an alternative design was feasible," *id.* (emphasis added), the factual findings and analysis of the Amended Master Complaint in this case, *see supra*, do not compel allowing the desired discovery.

(S.D.N.Y. 2013) ("[A]n allegation that [defendant] could have manufactured a different product altogether, or that others have done so, does not itself make out a plausible claim of a design defect.").

The Court cannot say that the magistrate judge erred as a matter of law by deciding that discovery into the conductive heating device UB3 is not relevant, particularly when Plaintiffs sought a ruling on that very question in connection with their discovery requests.

Based on the files, records, and proceedings herein, and for the reasons stated above, IT IS ORDERED THAT:

1. Plaintiffs' objection to the magistrate judge's Order [Dkt. No. 279] is DENIED.
2. The magistrate judge's Order of March 6, 2017 [Dkt. No. 249] is AFFIRMED.

Dated: April 13, 2017

s/ Joan N. Ericksen
JOAN N. ERICKSEN
United States District Judge